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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,414	09/25/2001	Fumiyasu Hirai	12218/1	6930

7590 08/27/2002
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Washington, DC 20005

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/27/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,414

Applicant(s)

HIRAI ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed June 10, 2002. Claims 1-3 and 5 have been cancelled. Claim 4 had been amended. Applicant's submission of Exhibit A (a partial translation of Takeshi HONDA) is acknowledged.
2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objections and Rejections Withdrawn

3. In view of Applicant's amendment the following objections and rejections are withdrawn:
 - a) Objection to the specification, page 2, paragraph 2 of the previous Office action.
 - b) Rejection of claims 4 and 6-7 under 35 U.S.C. 112, second paragraph, page 2, paragraph 3 of the previous Office action.
 - c) Rejection of claims 4 and 6-7 under 35 U.S.C. 102(b), pages 4-5, paragraph 5 of the previous Office action.
4. The rejection under 35 U.S.C. 102(a) as being anticipated by Hirai et al is maintained for claims 4 and 6-7 the reasons set forth on pages 3-4, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Hirai et al teach a method for removing enterotoxin which comprises bringing a body fluid containing an enterotoxin into contact with the adsorbent. Hirai et al teach that the adsorbent comprises a compound which has a log P value of at least 2.50 wherein P is a partition coefficient in an octanol-water system and which is immobilized on a water-insoluble carrier (see the Abstract). Hirai et al teach that the water-insoluble carrier is a water-insoluble porous carrier which has an exclusion limit for globular protein of from 1×10^4 to 60×10^4 (see page 2). The method of Hirai, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to

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show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Hirai et al do not anticipate the claimed invention because the molecular weight of TSST-1 is 22,000 and the molecular weight of the claimed enterotoxin is a molecular weight of about 26,000-28,000 and the TSST-1 and enterotoxin differ in chemical structure and lacks substantial homology. Applicant further urges that Hirai et al do not provide motivation for using adsorbents.

Applicant's arguments filed June 10, 2002 have been fully considered but they are not persuasive.

Applicant appears to be arguing limitations that are not in the claims. Limitations such as molecular weight and % homology are not recited in the claims. The claims are drawn to method of adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent to adsorb and remove the enterotoxin, said adsorbent comprising a compound with a P long, which P represents a partition coefficient in an octanol-water system, value of not less than 2.50 immobilized on a water-insoluble carrier. Hirai et al teach that toxic shock syndrome 1 (TSST-1) in body fluids can be efficiently removed by the adsorbent (see the Abstract). It is well known in the art that Staphylococcal enterotoxins, TSST-1 and the streptococcal pyrogenic toxins all belong to a family of superantigens (Schlievert, 1993 and Mehrotra, 2000). It also well known in the art that there is 96% agreement between the PCR results for detection of Staphylococcal enterotoxin D and

TSST-1 (Mclauchlin, 2000). Therefore, one could reasonable conclude barring evidence to the contrary, that the removal of enterotoxins would also include the removal of TSST-1. It is the Examiner's position that there is nothing on the record to show that the teaching of Hirai et al do not anticipate the claimed invention. Applicant has provided no side-by-side comparison to show that the claimed method of adsorptive removal of an enterotoxin is different from the method of adsorptive removal of an enterotoxin of the prior art.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

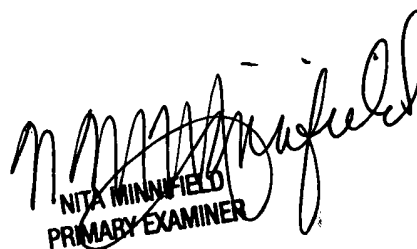
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6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.


Vanessa L. Ford
Biotechnology Patent Examiner
August 16, 2002


NITA MINNIFIELD
PRIMARY EXAMINER